Aventis Pharmaceuticals Inc.

Aventis

Patent Department

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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June 16, 2000

VIA HAND DELIVERY

Re: **Docket No. 00D-1197**

Dear Sir/Madame

The undersigned, on behalf of Aventis Pharmaceuticals, Inc. ("Aventis") offers the following comments on FDA's March 30, 2000 "Guidance for Industry on Court Decisions, ANDA Approvals, and 180-day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" ("Guidance") (65 Fed. Reg. 16922).

The Guidance states that in light of two court rulings, Torpharm v. Shalala, No. 97-1925 (D.D.C. 1997) and Mylan v. Shalala, No. 99-2995 (D.D.C. 2000), the FDA has reversed its longstanding interpretation of what "court" decision is sufficient to (a) terminate the statutory 30 month moratorium on ANDA approval and (b) trigger the statutory 180 days of market exclusivity for the first paragraph IV ANDA applicant. Previously, the FDA required that the court decision be a "final decision of a court from which no appeal can or has been taken." 21 CFR 314.107 (e). Henceforth, according to the Guidance, the relevant court decision will be that of "the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed," 65 Fed. Reg. at 16923, even if that decision is on appeal. Aventis believes that this reversal of position is unwarranted and unwise.

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The Guidance does *not* state that the FDA now believes that its prior interpretation of the statute was incorrect. Nor does the FDA state that its new interpretation is a correct reading of the statute, or that it is consistent with statutory intent or the policies underlying the Hatch-Waxman Act. Rather, the Guidance simply states that the *Torpharm* and *Mylan* cases have created "uncertainty" and that the "primary concern for the agency has been to identify an approach that will minimize further disruption and will provide the regulated industry with reasonable guidance for making future business decisions." 65 Fed. Reg. at 16923.

This is not a proper basis for reversing a longstanding agency interpretation of the statute, consistently adhered to by the FDA since at least 1989 when it first proposed the regulations in question. *Proposed Abbreviated New Drug Application Regulations*, 54 Fed. Reg. 28872 (July 10, 1989). The FDA's longstanding interpretation was set forth in formal regulations which were adopted after notice, comment and careful consideration by the agency of the policies underlying the Hatch-Waxman Act. It should not be set aside lightly simply because a single district court disagreed.[1]

In its 1989 Notice, the FDA observed that there was a "potential ambiguity in the statutory language concerning what 'court' decision triggers an effective date" and proposed that the court rendering the decision be "the court that enters final judgment from which no appeal can be or has been taken." 54 Fed. Reg. at 28894, 28929. FDA received only five comments regarding its interpretation of "the court," three of which supported the FDA's proposal and two of which argued that the "court" should be the district court. *Abbreviated New Drug Application Final Regulations, Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50354 (October 3, 1994). The FDA considered and expressly rejected those comments, and stated sound reasons for doing so:

[1]Although the government has decided not to appeal, the *Mylan* decision does not by itself void the FDA's regulatory interpretation because the principles of non-mutual issue preclusion ("collateral estoppel") do not apply to the United States Government. *See United States v. Mendoza*, 464 U.S. 154 (1984).

> FDA declines to amend § 314.107(e)(1) as suggested by the comments. To construe "the court" as a district court, regardless of any appeal of the district court decision, would deny the benefits of exclusivity to a prudent applicant that delayed marketing its product until resolution of an appeal by the patent holder . . . . Moreover, if the patent holder appealed the district court decision and were able to obtain a stay or an injunction against the marketing of the applicant's product, the applicant could lose the entire 180-day exclusivity period before the stay or injunction were lifted.
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> Given these considerations, FDA believes that any reference to "the court" must be the court that enters final judgment from which no appeal can be or has been taken. . . . This interpretation avoids potentially premature decisions on the effective date of ANDA approval and the loss of 180-day exclusivity.

Time and again, the FDA revisited its interpretation and adhered to it. *See, e.g., Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications*, 62 Fed. Reg. 63268, 63269 (November 28, 1997) ("While *Torpharm* is pending on appeal, FDA will continue to interpret the statute as described in § 314.107(e), which defines 'the court' as 'the court that enters final judgment from which no appeal can be or has been taken'"); *Effective Date of Approval of an Abbreviated New Drug Application*, 62 Fed. Reg. 59710, 59711 n.2 (November 5, 1998) ("The agency interprets the term 'court' to refer to the court that enters final judgment from which no appeal can be or has been taken (§ 314.107 (e))"). As recently as August 6, 1999, the agency stated:

> FDA's current regulations state that for purposes of applying the ANDA approval and exclusivity provisions of the statute, "the court" is the court that enters final judgment from which no appeal can be or has been taken (district court or appellate court) . . . .
>
> . . . FDA . . . proposes to maintain its current interpretation. The agency believes this interpretation is most consistent with the statutory scheme.

180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42879 (August 6, 1999) (emphasis added).

Moreover, the agency vigorously defended its interpretation in court. In the *Mylan* action, for example, the FDA argued:

> "FDA's interpretation preserves the important exclusivity incentive provided to the first ANDA applicant who challenges an innovator's patents.
>
> It is reasonable to avoid forcing an ANDA applicant to use its 180 days of exclusivity while fighting an appeal by the patent holder. FDA's interpretation also avoids the confusion in the marketplace and the disruption to patient care that could result if FDA issued an approval based on a district court decision that was later withdrawn when the decision was reversed by a court of appeals.

Federal Defendants' Opposition to Plaintiff's Motion for Summary Judgment, dated December 15, 1999 at 5.

Moreover, if Congress had disagreed with the FDA's longstanding and well-considered interpretation, it had ample opportunity to correct the agency when it enacted the Food and Drug Modernization Act of 1997, which specifically addressed, among other things, the ANDA approval and exclusivity provisions. *See* 21 U.S.C. § 355a (a). As the Supreme Court has stated, "[i]t is well established that when Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the 'congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'" *CFTC v. Schor*, 478 U.S. 833, 846 (1986) (citation omitted).

In proposing the new interpretation set forth in the Guidance, the FDA does not purport to be guided by the intent of Congress or by the policies underlying the statutory scheme. Rather, FDA states that its "primary concern" is to "minimize further disruption and . . . provide the regulated industry with reasonable guidance for making future business decisions." 65 Fed. Reg. at 16923. Assuming that it is appropriate for the FDA to make the avoidance of "disruption" its primary concern (as opposed to ascertaining the most reasonable interpretation of the statute), FDA's new interpretation does not further that goal. To the contrary, as the FDA stated to the Court last December, interpreting the "court" decision to be that of the district court -- as the Guidance does -- will only bring about "confusion in the marketplace and the disruption to patient care that could result if FDA issued an approval based on a district court decision that was later withdrawn

when the decision was reversed by a court of appeals." Federal Defendants' Opposition to Plaintiff's Motion for Summary Judgment in *Mylan* at 5.

Because federal judges in the district courts and regional circuits are oftentimes unversed in the subtleties of patent law, Congress established a specialized court of appeals, the United States Court of Appeals for the Federal Circuit, to hear patent appeals. A substantial percentage -- "hovering near 50%"[2] -- of patent decisions of district courts are *reversed* on appeal to the Federal Circuit. Thus, patent cases are not usually resolved at the district court level.

The clear intent of Congress in the Hatch-Waxman Act was to allow a 30-month period for patent claims to be resolved *before* FDA marketing approval for a potentially infringing product. It would subvert the statutory purpose for FDA to grant marketing approval within the 30-month period based solely on a district court decision which could well be reversed on appeal. That is because if the district court decision is reversed, *the patentee is relegated to remedies that Congress, in enacting the 30-month period, deemed to be inadequate*: (a) damages, which could be beyond the means of the infringing generic to pay, and (b) an injunction, which may be difficult in practice to obtain. Moreover, when a generic manufacturer enters the market based on an erroneous district court decision, the market is irrevocably altered. Even if the generic drug maker is subsequently enjoined, the patentee's loss of market share and market goodwill is irreversible.

As the FDA previously recognized, interpreting "court" to mean the district court puts a generic who prevails at the district court level in a quandary: it must launch its product immediately or lose the 180-statutory exclusivity period to which it is entitled. But if it does launch its product immediately, it faces the substantial risk that its victory in the district court will be reversed and that it will have to pay enormous infringement damages to the patentee.

Finally, FDA marketing approval based on an erroneous district court decision could have severe adverse effects on patient care. It is hardly in the best interests of patients for them to begin

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[2]*Cybor Corp. v. FAS Technologies Inc.*, 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Rader, dissenting).

a treatment regimen with a drug product that is only temporarily placed on the market based an erroneous decision by the district court -- only to have them interrupt the treatment regimen upon reversal by the Federal Circuit. The FDA's new interpretation will create uncertainty and confusion about what drugs will remain on the market and for how long, to the prejudice of patentees, generic companies and the public.

Another source of uncertainty is that the Guidance does not specify what constitutes a "decision." Under the Federal Rules of Civil Procedure, the general rule is that a decision of a district court "which adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties shall not terminate the action as to any of the claims or parties, and the order or other form of decision is subject to revision at any time before the entry of judgment adjudicating all the claims and the rights of all the parties." Fed. R. Civ. P. 54(b). In other words, until there is a final appealable judgment, any "decision" of the district court is subject to revision *even by the district court*. Fortunately, the FDA can remove this particular source of uncertainty by specifying that the "decision" of the court must be a judgment as defined by Fed. R. Civ. P. 54(a).

In sum, the FDA should continue to abide by its longstanding and consistent interpretation of the statute.

Sincerely,

Louis J Wille, Esq.
Vice-President, Global Patent Litigation